Notice of Allowability	Application No.	Applicant(s)	
	10/534,383	BONNEY ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the telephone interviews 1/22/09 & 1/26/09* .

2. ☒ The allowed claim(s) is/are *1,3,4,6,9-22,24-29,31-33 and 36-42*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *Attached* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Clinton Ostrup/ Examiner, Art Unit 3771	/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Jeffery L. Wilson on January 26, 2009.

The application has been amended as follows:

Claim 1. (Currently Amended) A hand-operated drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container ~~in conjunction with the inhalation by the patient~~, the device comprising:

a dispensing unit adapted to receive the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device ~~to deliver the drug composition as the patient inhales through the outlet~~, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

a casing unit for the dispensing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;

and wherein:

the dispensing and casing units have securing features for fixedly securing the units together;

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;

in the closed state, the casing unit is configured to enclose the dispensing unit with the container received therein; [[and]]

the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit;

the dispensing unit is adapted to receive the container such that, when the dispensing unit is independent from the casing unit, the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part; and

the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part and,

when the casing unit is in the closed state, the first part of the container is inaccessible to the digit of the patient's hand.

Claim 22. (Currently Amended) A method of manufacturing a hand-operated drug delivery device for delivery of a drug formulated in a drug container which is adapted to be placed in a dispensing mode on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container ~~in conjunction with the inhalation by the patient~~, the method comprising the steps of:

providing a dispensing unit for receiving the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug formulation is dispensed on application of the actuating condition to the container ~~to deliver the drug composition as a patient inhales through the outlet~~, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

separately providing a casing unit adapted to fixedly hold the dispensing unit such that the drug is dispensable from the container by the dispensing unit when held by the casing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;

and wherein:

the dispensing and casing units have securing features for fixedly securing the units together;

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;

in the closed state the casing unit is configured to enclose the dispensing unit with the container received therein; [[and]]

the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit;

the dispensing unit is adapted to receive the container such that, when the dispensing unit is independent from the casing unit, the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part; and

the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part and, when the casing unit is in the closed state, the first part of the container is inaccessible to the digit of the patient's hand.

Claim 38. (Currently Amended) A hand-operated drug delivery device for delivering to a patient a drug composition from a container which contains the drug

composition, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container, the device comprising:

a dispensing unit adapted to receive the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

a casing unit for the dispensing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet, the casing unit comprising a container member which defines a cavity in which the dispensing unit is releasably, fixedly securable, and a cover member which is movably mounted on the container member for movement between closed and open positions relative to the cavity to respectively place the casing unit in the closed and open states;

and wherein:

the dispensing and casing units have securing features for fixedly securing the units together;

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;

in the closed state, the casing unit is configured to enclose the dispensing unit with the container received therein;

the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit; and

wherein the dispensing unit is adapted to receive the container such that, when the dispensing unit is independent from the casing unit, the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part and wherein the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part and, when the casing unit is in the closed state, the first part of the container is inaccessible to the digit of the patient's hand.

Claim 42. (Currently Amended) A hand-operated drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition, the device comprising:

a container that includes a drug composition therein, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container;

a dispensing unit adapted to receive the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and

a casing unit for the dispensing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;

and wherein:

the dispensing and casing units have securing features for fixedly securing the units together;

the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;

the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;

in the closed state, the casing unit is configured to enclose the dispensing unit with the container received therein;

the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit; and

wherein the dispensing unit is adapted to receive the container such that, when the dispensing unit is independent from the casing unit, the first part is accessible to a digit of a patient's hand to enable the digit to move the first part relative to the second part and wherein the casing unit is adapted such that when fixedly secured with the dispensing unit, and in the open state, the first part of the container is accessible to the digit of the patient's hand to enable the digit to move the first part relative to the second part and, when the casing unit is in the closed state, the first part of the container is inaccessible to the digit of the patient's hand.

Claim 43 (CANCEL) ~~A method for delivering to a patient a drug composition from a container which contains the drug composition using a hand-operated drug delivery device, the container adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which comprises movement of a first part of the container relative to a second part of the container in conjunction with the inhalation by the patient, the method comprising:~~

~~providing a drug delivery device comprising:~~

~~(i) a dispensing unit adapted to receive the container, the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container and an outlet through which the drug composition is dispensable from the device, the actuating mechanism configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container; and~~

~~(ii) a casing unit for the dispensing unit, the casing unit configured to be movable between a closed state in which the casing covers the outlet, and an open state in which the casing unit uncovers the outlet;~~

~~and wherein:~~

~~(iii) the dispensing and casing units have securing features for fixedly securing the units together;~~

~~(iv) the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state;~~

~~(v) the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit;~~

~~(vi) in the closed state, the casing unit is configured to enclose the dispensing unit with the container received therein; and~~

~~(vii) the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit;~~

~~opening the casing unit to an open state;~~

~~placing the outlet of the dispensing unit into a mouth of the patient; and~~

~~hand-operating the actuating mechanism of the dispensing unit to apply the actuating condition to the container to deliver the drug composition as the patient inhales through the outlet.~~

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771